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Your Ref:

My Ref:
2244/PCT

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European Patent Office
PB 5818 Patentlaan 2
NL-2280 HV Rijswijk
The Netherlands

Dear Sirs,

Re: International Patent Application No. PCT/GB2004/004895
Dispenser & Reservoir

I write further to the Written Opinion dated 24th February 2005 and following the filing of the IPED on 21st June 2005.

In the Written Opinion the examiner has suggested that all the claims of the present invention lack novelty over prior art US 5 878 917 Reinhard, referred to by the examiner as D1, US 4 620 670 Hughes, referred to by the examiner as D2 and US 2002.043262 Langford, referred to by the examiner as D3. I submit that all of these citations relate to a very different invention to that of the application in suit.

The present invention relates to the provision of a dispenser having a reservoir whose contents can be readily estimate, so that a user knows how many doses remain, particularly as the dispenser approaches exhaustion. In order to achieve this a portion of the reservoir is provided with a relatively small cross-section so that a use can see a comparatively large change in the level and thus easily estimate the doses left.

Reinhard teaches a dispenser having a reservoir made of glass to aid viewing of the contents thereof. However, the shape of the reservoir simply follows the shape or standard canisters. There is no significant narrowing of the reservoir to enable determination of the amount of contents therein. The diagrams show shaping of the reservoir a little over half way down, but this does not constitute provision of a section having a small cross-section to allow a user to note a comparatively rapid depletion of the quantity of substance remaining, I submit. The reduction in the cross-section is not sufficiently significant to register a small decrease in the medicament, as in a single dose, resulting in a comparatively large drop in the level of medicament in this section. Thus this does not enable a

to determine the quantity of medicament remaining in the inhaler. I therefore submit that this citation does not destroy the novelty of the application in suit.

Hughes teaches a nebuliser having a reservoir provided with a conical base. This allows the medicament to pool in the apex of the cone, ensuring that all the medicament is used and none be wasted. This conical area is very shallow and is effectively a slight dip in the base of the reservoir. Being so shallow a small reduction in the quantity of medicament does not represent a comparatively large drop in the level of the medicament. In addition, by the time the medicament has reached the level of this conical area, there is so little left that the user cannot use this to determine when he needs to get a new inhaler, or whether there is sufficient medication for a weekend away or even a day out. Thus, I submit, this cannot be said to be a section having a small cross-section to allow a user to note a comparatively rapid depletion of the quantity of substance remaining as required by claim 1 of the application in suit.

The final citation Langford teaches an inhaler having a canister or reservoir. The reservoir is provided with a transparent viewing window, to enable to user to see the quantity of medicament remaining in the reservoir. In addition the reservoir narrows slightly towards the attachment of its valve. However, the viewing window does not extend into this area. Thus, although there is an area having a reduced cross section, this area does not allow a user to note a comparatively rapid depletion in the quantity of substance remaining. Therefore the teaching of this citation does not read on to claim 1 of the present application, I submit. In addition, the reduction in the cross-section of the reservoir is simply to enable to reservoir to be connected to the valve, and to ensure that as much medication as possible is used. Thus as in the previous citation, this area cannot act as a useful gauge to determine the amount of medication left.

Thus none of these citations, I submit, teach the present invention. Two of the citations, Reinhard and Langford relate to attempts to give a user an indication of the amount of medication left in the reservoir. This is important, particularly as the reservoir approaches exhaustion, so that the user can know when they need to obtain a further supply of the medication, and whether a particular reservoir has sufficient medication for a weekend away or even a day out. Inhaler users regularly have more than one inhaler in use at the same time, for example one by the bedside, one in a hand bag or sports bag, and possibly one in the car. In addition these will tend to get rotated to ensure that for example the one in the hand bag always has a reasonable quantity of medication in it so that if the user is out for the day or a night away, they will have sufficient medication. When this hand bag one appears low this may be changed with the one by the bed so that it can get used up and yet the user will generally have a spare one at home so when this one is exhausted the user is not left with no medication.

I submit that the devices of neither the Reinhard citation nor the Langford citation fully achieve this objective. In the Reinhard citation the intention is that the user turns the inhaler upside down relative to use so that the medication appears in the exposed part of the reservoir. This has the widest cross-section and so it is not easy to determine the amount of medication left. While there is a slight reduction in cross-section in the other part of the reservoir this is only a small reduction and anyway this part is hidden from sight by the dispenser. In the Langford citation a viewing window is provided in the reservoir but again this extends along the part of the reservoir having the widest cross-section. Although these is a reduction in cross-section, this is to fit the reservoir to its valve and ensure all the medication is used. Due to the shallowness of the reduction in cross-section it could not satisfactorily be used to determine the amount of medication remaining in the reservoir, and furthermore is hidden from view by the dispenser.

The Hughes citation teaches a nebuliser, rather than an inhaler. A nebuliser dispenses a single dose of medication and so there is no need to try and determine when the medication is exhausted. The patient breathes in the medication until the dose is exhausted and then takes another dose when required. This is very different from an inhaler, I submit, which contains many doses and thus it is of great benefit to the user to know approximately how many doses remain, particularly when the inhaler is approaching exhaustion, so that they are not stranded with no medication. In addition, as discussed above, and in relation to the Langford citation, the reduction in cross-section of the reservoir of the nebuliser cannot be used to determine the amount of medication remaining. Thus it does not destroy the novelty of the present invention.

One of the significant differences between these citations and the present invention, I submit, is that the portion of the reservoir having a reduced cross-section is distal from the source valve. As a result it extends out of the dispenser and can be used to determine the quantity of medication remaining, with a small decrease in the amount of medication remaining being converted into a relatively large drop in the level of medication in this portion. I submit that the use of a portion have a reduced cross-section to achieve this relatively large apparent decrease is not disclosed in any of the citations.

Thus I submit that none of the citations destroy the novelty and inventiveness of the application in suit.

I request that if the examiner does not accept these arguments he issues a further Written Opinion to give the applicant the opportunity to respond to his particular objections.

Yours faithfully

NIGEL BROOKS